



Pharmaceutical Market Access and Drug Safety Act (S. 334)

Introduced by Senators Byron L. Dorgan (ND), Olympia Snowe (ME), Charles Grassley (IA), Edward M. Kennedy (MA), John McCain (AZ), Debbie Stabenow (MI) and others

Senators Dorgan, Snowe, and others have introduced bipartisan prescription drug importation legislation, the Pharmaceutical Market Access and Drug Safety Act (S. 334). This bill would address the unfair price inequity for prescription drugs that currently exists in the world today. American consumers are currently charged 55 percent more, on average, for the same brand-name medicines sold in other major developed countries for a fraction of the price. S.334 would allow American consumers to benefit from international price competition for prescription medicine in two ways:

- 1) The bill allows U.S.-licensed pharmacies and drug wholesalers to import FDA-approved medications from Canada, Europe, Australia, New Zealand, and Japan and pass along the savings to their American customers. This approach would allow Americans to benefit from lower prices on their prescription drugs while still enabling them to use their local pharmacy.
- 2) The bill would allow individual consumers to import prescription drugs for their own personal use. More specifically, consumers would be able to purchase their medicines directly from safe, reliable, FDA-inspected Canadian pharmacies via mail-order or the Internet.

S. 334 includes a range of safety features intended to guarantee that only safe, effective FDA-approved prescription drugs are imported:

- Requires pharmacies and drug wholesalers to register with the FDA and be subject to frequent, random inspections.
- Allows only the importation of FDA-approved medicines with a “chain of custody” that can be traced all the way back to an FDA-inspected manufacturing plant.
- Allows for the use of anti-counterfeiting technology to identify safe, legal imported medicines.
- Gives the FDA the resources and authority it needs to ensure the safety of imported drugs and to stop those imports that are unsafe.

The bipartisan bill also includes a number of provisions intended to ensure that the drug industry cannot thwart the law and prevent consumers from reaping the benefits of drug importation:

- Allows drug importation to begin without first requiring certification by the HHS Secretary.
- Includes a “non-discrimination” provision that would make it an unfair and discriminatory act for drug manufacturers to get around the law by shutting down the supply of prescription drugs they make available to pharmacists and wholesalers, as they are currently doing in Canada.
- Also includes features to prevent a drug company from blocking importation by making subtle changes to a drug, such as changing the color or the place of manufacture, so that it is no longer FDA approved.